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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/542,718

Applicant(s)

YU ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the Amendment and Response filed March 15, 2002. Claims 1-2 and 4 have been amended and claim 6 has been canceled. Claims 1-5 are now pending and under consideration. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is NON-FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, second paragraph

3. Claims 1 and 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 remains rejected for failing to recite a final process step that clearly relates back to the claim preamble, and over the recitation of the term "a target sequence" and "the target sequence," for reasons set forth in the prior Office action. The response requests further explanation of the rejection, arguing that "the preamble of claim 3 recites a method of amplifying a beta-2 adrenergic receptor and step (b) of the claim recites the generation of at least one copy of the target (i.e., amplification)." However, as stated previously, while the claim preamble makes reference to a beta-2 adrenergic receptor target sequence, the actual method steps of the claim merely refer to a "target sequence." While the claim does require the use of particular primers, the

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claim is not written in such a way so as to actually require, e.g., hybridization of primers under high stringency conditions, specific amplification of a particular target molecule, etc. As it appears that the actual steps of the claim could be used to amplify target molecules other than beta-2 adrenergic receptor target sequences, it is not clear whether the claimed method is in fact one for amplifying only such sequences or whether the claim encompasses something broader. It is noted that this rejection could be overcome by amending the recitation "a target sequence" in step (a) to recite "the target sequence" (such that this term clearly refers back to the previously recited beta-2 adrenergic receptor target sequence).

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS' AMENDMENTS:

Claims 1 and 3-4 are indefinite over the recitation of the phrase "A composition of matter consisting of SEQ ID NO 2 and SEQ ID NO 3" in claim 1. It is not clear whether this language encompasses a composition of matter consisting of 2 different nucleic acid molecules (specifically, a nucleic acid molecule consisting of SEQ ID NO 2 and a nucleic acid molecule consisting of SEQ ID NO 3), or whether the claim as amended is intended to encompass, e.g., a single molecule consisting of SEQ ID NO 2 followed by SEQ ID NO 3, or SEQ ID NO 3 followed by SEQ ID NO 2 (which molecules were not disclosed in the originally filed specification; see new matter rejection below).

Clarification is required.

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY**APPLICANTS' AMENDMENTS:**

5. Claims 1 and 3-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 (from which claims 3-4 depend) has been amended to recite "A composition of matter consisting of SEQ ID NO 2 and SEQ ID NO 3." While the originally filed specification discloses amplification primers consisting of SEQ ID NO 2 and SEQ ID NO 3, respectively, the specification does not disclose any molecules consisting of only these two particular sequences. Accordingly, Applicants' amendment of the claim in this manner introduces new matter.

Claim Rejections - 35 USC § 102

6. In view of Applicants' amendment of claim 1 to recite a composition "consisting of SEQ ID NO 2 and SEQ ID NO 3" and of claim 2 to require first and second nucleic acids comprising SEQ ID Nos 2 and 3, the rejection of claims 1-2 under 35 USC 102(b) as being clearly anticipated by Drazen et al is withdrawn.

Claim Rejections - 35 USC § 103

7. In view of the cancellation of claim 6, the rejection of the claim under 35 USC 103(a) as being unpatentable over Dewar et al in view of Drazen et al and Matalon et al is moot.

8. Claims 1-5 are rejected under 35 USC 103(a) as being unpatentable over Dewar et al in view of Drazen et al and Matalon et al, for reasons set forth in the Office action of October 11, 2000.

The response traverses the rejection on the grounds that "Nothing in Drazen, Dewar, or Matalon teaches or even suggests the particular oligonucleotides recited in the pending claims, nor that "any" combination of oligonucleotides would be suitable for the detection or amplification of 2 targets," and notes that "Claims 1 and 2 no longer recite the term 'comprising,' but rather now recite the term 'consisting of.'"

Applicants' arguments have been thoroughly considered but are not persuasive. First, with regard to claim 2, it is noted that the claim has not in fact been amended to recite "consisting of." Regarding claim 1, while the claim has been amended to set forth the "consisting of" language, it is noted that the prior Office action specifically stated that the instant rejection applied to the claims to the extent that they might be limited to a primer pair consisting of SEQ ID Nos 2 and 3 and to a probe selected from SEQ ID NO: 4 and 5. The rejection further indicated why and how one of ordinary skill in the art would have selected and prepared these molecules to achieve rapid detection of a polymorphism in codon 16 of the beta-2 adrenergic receptor gene. While the response states Applicants' belief that the combination of references does not teach or suggest

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the claimed invention, the response does not indicate why this is the case, or provide any type of reasoning to support Applicants' assertion. Accordingly, Applicants' arguments are not persuasive.

The combined references of Dewar et al, Drazen et al, and Matalon et al suggest all the limitations of present claims 1-5, and therefore this rejection is maintained.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 3, and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7 of U.S.

Patent No. 6,593,092. An obviousness type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d

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1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

With regard to instant claims 1 and 5, although the conflicting claims are not identical, they are not patentably distinct from each other because claims 4-7 of the '092 patent encompass compositions including a primer consisting of SEQ ID NO: 2 and a primer consisting of SEQ ID NO: 3. Claims 6-7 of the '092 patent encompass a kit that anticipates the kit of instant claim 5 (see items (a) and (b)), while component (a) of the kit alone anticipates instant claim 1. Further, with regard to claims 4-5 of the '092 patent, it would have been obvious to one of ordinary skill in the art to have prepared a composition of matter consisting of SEQ ID Nos 2 and 3, given that these two primers are specifically disclosed for use together in step (a) of claims 4-5.

With regard to instant claim 3, the invention of this claim is anticipated by claims 4-5 of the '092 patent (see in particular steps (a) and (b) of the '092 patent), and is therefore not patentably distinct from the invention of '092 claims 4-5.


Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Diana B. Johannsen
Primary Examiner
Art Unit 1634
August 22, 2005